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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,745	02/11/2002	Peter G. Schultz	220032001301	2759

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[REDACTED] EXAMINER

BAKER, MAURIE GARCIA

[REDACTED] ART UNIT

[REDACTED] PAPER NUMBER

1639

DATE MAILED: 04/09/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

file

Office Action Summary	Application No. 10/074,745	Applicant(s) Schultz et al	
	Examiner Maurie G. Baker	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Jan 21, 2003

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 94-163 is/are pending in the application. i28, i46-i50, i53-i57, i59-i62

4a) Of the above, claim(s) 104, 105, 108-111, 113, 114, 117-120, 122, 125, is/are withdrawn from consideration. i51, i52, i58 & i63

5) Claim(s) _____ is/are allowed.

6) Claim(s) 94-103, 106, 107, 112, 115, 116, 121, 123, 124, 126, 127, 129-145, is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 & 7

4) Interview Summary (PTO-413) Paper No(s). _____

5) Notice of Informal Patent Application (PTO-152)

6) Other:

DETAILED ACTION

1. Applicant's Response filed January 21, 2003 (Paper No. 9) and Response filed August 30, 2002 (Paper No. 5) are acknowledged. In Paper No. 5, claim 163 was added. Thus, claims 94-163 are pending.

Restriction/Election

2. Applicant's election of species and remarks in Paper No. 9 are noted with appreciation. The election is now deemed fully responsive.

3. As indicated by applicant, claims 94-103, 106, 107, 112, 115, 116, 121, 123, 124, 126, 127, 129-145, 151, 152, 158 and 163 read on the elected species. Therefore, claims 104, 105, 108-111, 113, 114, 117-120, 122, 125, 128, 146-150, 153-157 and 159-162 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to non-elected species, there being no allowable generic claim.

4. Thus, claims 94-103, 106, 107, 112, 115, 116, 121, 123, 124, 126, 127, 129-145, 151, 152, 158 and 163 are examined on the merits in this action.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 163 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The specification as originally filed does not provide support for the invention as now claimed. Claim 163 recites a specific method for “evaluating an array of polycarbonate polymer materials” that recites specific methodologies therein. Although some of the generic concepts in the claim are present in the instant specification, there is *no indication* that the specific combination set forth in claim 163 was contemplated. Note that a broad generic disclosure is **not** sufficient support for a specific entity within the class. Also, in accordance with MPEP § 714.02, applicants **should specifically point out support** for any amendments.

7. Claims 94-103, 106, 107, 112, 115, 116, 121, 123, 124, 126, 127, 129-145, 151, 152, 158 and 163 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application

was filed, had possession of the claimed invention. This is a written description rejection.

There are a virtually unlimited number of compounds that would fall within the claimed genus of “polymeric materials” (i.e. “non-biological organic polymers”). This is because the instant claims give *no structure* as to the particular polymers and thus the claims could encompass an infinite number of variations. However, the instant description discloses the preparation of only a very limited number of such compounds. It is noted that instant claim 163 does recite a specific material, namely “polycarbonate polymer materials”. However, such limitation is deemed to be new matter as it is not supported by the instant disclosure (see rejection above) and thus this claim is also included in the written description rejection as it is not adequately described.

The present application fails to describe sufficient examples of preparing or evaluating arrays of “non-biological organic polymers” that are within the scope of the presently claimed invention. The instant description discloses the preparation of only **one** array of such polymers, an array of 16 polymers formed by the polymerization of styrene with acrylonitrile and the evaluation of the array for only **one** property (hardness). Applicant’s claimed scope represents only an invitation to experiment regarding possible compounds.

With respect to adequate disclosure of the scope of the presently claimed generic applicant is referred to the discussion in *University of California v. Eli Lilly and Co.* (U.S. Court of Appeals Federal Circuit (CAFC) 43 USPQ2d 1398 7/22/1997 Decided July 22, 1997; No. 96-1175) regarding disclosure. For

adequate disclosure, like enablement, requires representative examples which provide reasonable assurance to one skilled in the art that the compounds falling within the scope both possess the alleged utility and additionally demonstrate that applicant had possession of the full scope of the claimed invention. See *In re Riat et al.* (CCPA 1964) 327 F2d 685, 140 USPQ 471; *In re Barr et al.* (CCPA 1971) 444 F 2d 349, 151 USPQ 724 (for enablement) and *University of California v. Eli Lilly and Co.* cited above (for disclosure). The more unpredictable the art the greater the showing required (e.g. by “representative examples”) for both enablement and adequate disclosure.

Thus, the disclosure is neither representative of the claimed genus, which encompasses any “non-biological organic polymers”, nor does it represent a substantial portion of the claimed genus. Moreover, the claimed genus encompasses members which are yet to be prepared or envisioned. This further evidences that the structural features of the exemplified compounds do not constitute support for the claimed genus or a substantial portion thereof.

8. Claims 94-103, 106, 107, 112, 115, 116, 121, 123, 124, 126, 127, 129-145, 151, 152, 158 and 163 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for arrays of polymers formed by polymerization of styrene with acrylonitrile and screening such arrays for a physical property, does not reasonably provide enablement for making an array of any type of “non-biological organic polymers” and screening the array for any “property of interest” as broadly called for in the claims. The specification does not enable any person skilled in the art to which

it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

It is clear from applicant's specification how one might practice this invention with arrays of polymers formed by polymerization of styrene with acrylonitrile; however, there is insufficient guidance as to how to make/use any array of polymeric materials. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors can include, but are not limited to:

- (1) the breadth of the claims;
- (2) the nature of the invention;
- (3) the state of the prior art;
- (4) the level of one of ordinary skill;
- (5) the level of predictability in the art;
- (6) the amount of direction provided by the inventor;
- (7) the existence of working examples; and
- (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

(1-2) The breadth of the claims and the nature of the invention: The claims recite a method of preparing and/or evaluating an array of polymeric materials on a substrate. The polymeric materials are recited as "non-biological organic polymers". No other structural limitations on the polymers are given and, as such, this could read on a wide variety of structures. Such represents very broad scope. Again, it is noted that claim 163 does recite a specific structure; however, those limitations are deemed to be new matter as they are not supported by the instant

disclosure (see rejection above) and thus are also not enabled by the instant specification.

(3 and 5) The state of the prior art and the level of predictability in the art:

Methods for making and testing arrays of polymeric materials were known at the time of filing; however, only limited numbers of such arrays were known and the specification gives no guidance to permit one of skill in the art to devise strategies for synthesis of an array of *any* “non-biological organic polymers”. The structures of possible variants are sufficiently diverse and one of ordinary skill would not be able to predict such structures. Applicant’s claimed scope of compounds represents only an invitation to experiment regarding possible compounds (see also above concerning written description and cases cited therein).

(4) The level of one of ordinary skill: The level of skill would be high, most likely at the Ph.D. level. However, such persons of ordinary skill in this art, *given its unpredictability*, would have to engage in undue (non-routine) experimentation to carry out the invention as claimed.

(6-7) The amount of direction provided by the inventor and the existence of working examples: Applicants have only exemplified the preparation of **one** array of such polymers, an array of 16 polymers formed by the polymerization of styrene with acrylonitrile and the evaluation of the array for only **one** property (hardness). No generic strategy for preparing and/or evaluating any array of polymers is given. One of ordinary skill could not guess, *a priori*, how to make and use arrays of undefined polymeric materials.

(8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure: The claims contain only the broad recitation of “polymeric material” or “non-biological organic polymer” and various broadly recited properties “of interest”. However, the instant specification does not provide to one skilled in the art a reasonable amount of guidance with respect to the direction in which the experimentation should proceed in carrying out the full scope of the claimed methods. Note that there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and use the invention as broadly as it is claimed. *In re Vaeck*, 947 F.2d 488, 496 & n.23, 20 USPQ2d 1438, 1445 & n.23 (Fed. Cir. 1991). Therefore, it is deemed that further research of an unpredictable nature would be necessary to make or use the invention as claimed. Thus, due to the inadequacies of the instant disclosure, one of ordinary skill would not have a reasonable expectation of success and the practice of the full scope of the invention would require undue experimentation.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
10. Claims 94-103, 106, 107, 111, 115 and 116 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 94 (and all claims that depend therefrom) is indefinite because it is incomplete. The claim is drawn to a “method of evaluating an array of polymeric materials”. However, the claim *only* contains preparation steps. There are no “evaluation” steps present whatsoever. This is confusing and unclear as to applicant’s intent.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 94-103, 106, 107, 112, 115, 116, 121, 123, 124, 126, 127, 129-145, 151, 152 and 158 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rolleston et al (US 5,416,613; on PTO-1449) and Howard et al (US 3,868,221; on PTO-1449) in view of Baldeschwieler et al (US 5,847,105; on PTO-1449) and Leasure et al (Inorg. Chem. 33(7), 1994; on PTO-1449) and Gallop et al (J. Org. Chem. 37(9), 1994; on PTO-1449).

The claimed invention is directed to the generation of arrays of “non-biological organic polymers” and testing such arrays for desired polymer properties. Arrays of materials for testing were well known at the time of filing. See, for example, Rolleston et al, Abstract and Figure 2. A wide variety of “non-biological organic polymers” within the scope of the presently claimed invention are known in the art. Testing polymers was also well-known. See, for example, Howard et al. Howard et al teaches testing of several samples of polymer for resistance to thermal degradation (see Abstract). A plurality of samples are tested to identify ones that have superior thermal stability (see Examples and patented claim 10).

Baldeschwieler et al teaches a method for the synthesis of arrays of chemical compounds (see Abstract and Figure 1A). A dispenser is used to form arrays of microdrops that are spatially defined, see Figure 1A and 2. Specifically, the dispenser is an ink-jet device (see column 9 line 16 through column 10 line 29). Baldeschwieler et al specifically teaches that small molecules can be made that “need not be polymeric molecules where there is a repetitive unit” (column 7 lines 52-53). Baldeschwieler et al lacks the specific teaching of the materials being non-biological organic polymers. However, as noted above, the reference

states that the materials "need not be polymeric molecules where there is a repetitive unit" (column 7 lines 52-53) which certainly does not preclude non-biological organic polymers but would exclude biological polymers as defined in the instant invention (for example, peptides).

Also, spatially defined arrays of polymeric materials were well known in the art at the time of the invention, as taught by Leasure et al. Leasure et al teaches a method for preparing spatially defined polymeric substances on the micron scale. Although the arrays of Leasure et al are made by lithography, the method of synthesizing in the reference reads on the claimed method of preparation. Also, it would be obvious to the skilled artisan that when employing the teachings of Baldeschwieler et al one could add the necessary reagents in whatever order and/or concentration was necessary for the reaction.

Baldeschwieler et al discusses the addition of reagents via a microdrop in column 7 line 64 through column 8 line 5. Also discussed in this section is the fact that a reagent could be added to the entire substrate at once (TFA mentioned at the top of column 8) and the fact that the reagents can be different (different amino acids and aminobenzophenones in the synthesis of benzodiazepines). It would furthermore be obvious to the skilled artisan that a pipette and an ink-jet device would produce the same effect (albeit on different scales) and Baldeschwieler et al discusses a microdrop dispensing device in general before the specific discussion of an ink jet nozzle.

Additionally, Baldeschwieler et al lacks the specific teaching of the number of the materials in the array (when the materials are other than biological

organic polymers) and of the specific screening techniques of the claims.

However, the reference does teach very large numbers of biological materials can be made (see column 6 and column 7 lines 31-40) and it would be obvious to the skilled artisan that one could make a similar number of other materials by the method of Baldeschwieler et al. Also, the reference discusses several detecting means (column 9 lines 7-11); again, these could be used on any appropriate material. Additionally, it was well known in that art that such arrays could be made and tested by a variety of techniques. The advantages (e.g. relatively fast and efficient easy assays etc.) and application of parallel combinatorial arrays for generating and optimizing properties were known in the prior art. Gallop et al teaches the general tenets of combinatorial chemistry, stressing the importance of screening on page 1234. Gallop et al also teaches the basics of “creating chemical diversity from a basis set” – see Figure 1. Further, varying monomers, initiators, etc. for generating such arrays would be routine optimization in view of the above teachings.

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to perform the method of Baldeschwieler et al to make non-biological organic polymers, such as those taught by Howard or Leasure et al, in spatially arrayed format for testing. It would have also been *prima facie* obvious to one of ordinary skill in the art at the time the invention perform the method of Baldeschwieler et al to make large arrays of materials other than biological organic polymers, and to screen such arrays as further taught by Gallop et al and Howard et al. A person of ordinary skill in the art would have

been motivated to do ^{so} have an array of materials for testing to find compounds of interest.

MB
4/14/03

Status of Claims/Conclusion

14. No claims are allowed.
15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie Garcia Baker, Ph.D. whose telephone number is (703) 308-0065. The examiner is on an increased flextime schedule but can normally be reached on Monday-Thursday and alternate Fridays from 9:30 to 7:00.
16. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang, can be reached at (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



MAURIE GARCIA BAKER PH.D.
PRIMARY EXAMINER

Maurie Garcia Baker, Ph.D.
April 6, 2003